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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,832	06/01/2001	Michel Sadelain	830002-2003.1	3724

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EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/872,832	SADELAIN ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) *10,16,17,23,26-33,37,39 and 41-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11-14,18-22,24,25,34-36,38 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group I and the species: cell source - human; cell type - fibroblast; accessory molecule - B7.1; HLA - A2.1; T cell epitope - E495, in the paper filed 6/10/04 is acknowledged.

Applicant argues that there is no undue search burden in the absence of a species election. In particular, Applicant argues that the searches are co-extensive and the search of any species would include the remaining species. Applicant further argues that the absence of a finding of lack of unity during international prosecution evinces that the species requirement should be withdrawn or reformulated. Applicant concludes by arguing that the claims of all Groups have identical classifications.

These arguments are not found persuasive for the following reasons. While the search of the individual species may overlap, they are not co-extensive. Whereas one reference might teach the artificial antigen presenting cell (AAPC) of the claims comprising a mouse cell, it might be silent regarding a human cell. Likewise, a reference teaching one antigen would not necessarily teach all of the others recited in the claims and/or disclosed in the specification. Accordingly, a showing of nonco-extensive searches has been accepted by the Office as a showing a serious search burden on the Examiner.

Regarding international prosecution, Applicant is advised that the instant case in not a national phase application and regardless, each application is examined on its own merits by the examiner of record.

Further regarding search burden and classification, while it has been noted that the Groups are classified in the same class, in the establishment of search burden, classification of subject matter is merely one indication of the burdensome nature of the search involved. In the biotechnological arts, the literature searches are generally far more important in evaluating burden of search. In the instant application, the claimed inventions consist of different products, and different methods. Clearly, different searches and different issues are involved in the examination of groups ranging from artificial cells to isolated T cells to *in vivo* methods of treating patients to *in vitro* screening assays. Accordingly, search burden has been established.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 41-66 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions. Claims 10, 16, 17, 23, 26-33, 37, and 39 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected species

Claims 1-9, 11-14, 18-22, 24, 25, and 34-36, 38, and 40 read on the elected invention and are being acted upon.

3. The declaration is objected to because uninitialed changes have been made to the address of Inventor Latouche. A new declaration is required.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-9, 11-14, 18-22, 24, 25, and 34-36, 38, and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically, the elected species of peptide "E495". Peptide E495 is disclosed but not described in the specification at page 40. In the election of species Applicant states that the sequence of the peptide is NLVMVATV and that a further description of the peptide can be found in Papanicolaou et al., *Blood*. 2003 Oct 1;102(7):2498-505. Applicant is advised that it is inappropriate to attempt to use a post-filing reference to define a claimed invention. Further, the reference fails to teach any "E495" peptide. While the reference does teach a **P**495 peptide, the sequence of the P495 peptide is NLV**P**MVATV. Accordingly, the metes and bounds of the elected invention cannot be determined.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same

and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-9, 11-14, 18-22, 24, 25, and 34-36, 38, and 40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the specification fails to show how to make the E495 peptide.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention.

A s set forth above, a review of the specification shows that the E495 peptide is disclosed just once (at page 40). All that is disclosed is that the peptide is derived from the CMV pp65 protein. While the pp65 protein is known in the art, a search of Medline for "E495" yields no relevant results. Accordingly, the sequence of the peptide cannot be known, thus, it cannot be made.

This limited disclosure is insufficient support for the AAPC of the instant claims. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Given the inherent unpredictability of physiological activity and the lack of sufficient specific guidance in the specification, it would take undue trials and errors to practice, i.e., make, the claimed invention.

8. The instant application claims the benefit of priority of U.S. Provisional Application 60/209,157, filed 6/02/00. The '157 application does not disclose the elected peptide species E495. Accordingly, the benefit of priority of the '157 application is denied. The priority date of the instant application is its filing date, 6/01/2001. Note that for search purposes the antigen of the instant claims is considered to be any CMV protein.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-9, 11-14, 18-22, 24, 25, and 34-36, 38, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Latouche et al. (2000) in view of Boeckh (1999).

Latouche et al. teaches an artificial antigen presenting cell comprising a human fibroblast expressing B7.1 and HLA A2.1 (which includes a human β2-microglobulin) from recombinant viruses, and presenting a T-cell specific epitope (see particularly page 405, Construction of AAPCs). Note that Claims 6, 7, 11, 12, 18, and 19, recite autologous or non-autologous, or endogenous or exogenous. These limitations, however, are only meaningful in specific contexts, i.e., a molecule is only autologous, non-autologous, endogenous, or exogenous depending on the context in which it is viewed. Thus, any molecule would be autologous in relation to its source and non-autologous in any other context. Likewise, any molecule would be endogenous in one context yet exogenous in any other. Accordingly, the limitations of the claims are met by the AAPC of the reference.

The reference teaching differs from the claimed invention only in that it does not teach the E495 (a CMV) antigen.

Boeckh teaches that CMV causes significant morbidity and mortality after hematopoietic stem cell transplantation (see particularly the abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention to produce an artificial antigen presenting cell comprising a human fibroblast expressing B7.1 and HLA A2.1 (which includes a human β2-microglobulin) from recombinant viruses, and presenting a T-cell specific epitope wherein the epitope is a CMV epitope. One of ordinary skill in the art at the time the invention was made would have been motivated to employ a CMV antigen given the teachings of Boeckh that CMV causes significant morbidity and mortality after hematopoietic stem cell transplantation, thus

teaching that additional tools for fighting CMV infection are needed.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

Please Note: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

G.R. Ewoldt, Ph.D.
Primary Examiner
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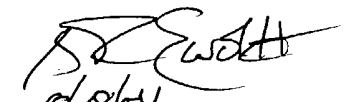

8/8/04

G.R. EWOLDT, PH.D.
PRIMARY EXAMINER